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14. ABSTRACT The purpose of this project is to study the effects on bone health of exoskeleton-assisted gait in individuals with a complete spinal cord injury. Advanced biomechanical models of human locomotion are utilized to estimate the mechanical effects of the dynamic loading of the bone structures that takes place during exoskeleton-assisted gait. The estimated maximum energy equivalent strain is studied as a potential proxy of bone adaptation and correlated with high-resolution peripheral quantitative computed tomography data and with clinical measures (e.g. biomarkers of inflammation such as C-reactive protein and IL-6) that are collected longitudinally. The research team has developed advanced biomechanical models to study the biomechanics of exoskeleton-assisted gait and derive estimates of loads applied to the bones. The research team continues to recruit study volunteers.					
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Introduction

People with Spinal cord injury (SCI) are often affected by an accelerated bone loss that occurs primarily at regions below the neurological lesion [1]. The severity of the impairment is directly proportional to the extent of bone loss [2] thus resulting in a greater loss in individuals with motor complete lesions [3]. Furthermore, immobilization after SCI is associated with the development of multiple complications such as decreased pulmonary function, systemic inflammation and loss of muscle mass [4-6].

For these reasons, remobilization is a primary clinical goal for individuals with SCI. The use of exoskeletons (such as the EksoTM system by Ekso Bionics) to achieve remobilization has become increasingly common in the rehabilitation setting [7].

The overall aim of this study is to rigorously quantify the motions of and the forces transmitted through the lower extremities during exoskeleton-assisted gait, and determine the specific effects of exoskeleton-assisted gait on bone health, muscle mass, and other clinical functional outcomes. The hypothesis of the study is that exoskeleton-assisted ambulation has skeletal and general health benefits for individuals with SCI that are proportional to the total stimulus delivered. To test this hypothesis, we plan to quantify the joint kinematics and kinetics, enabling us to estimate loads on lower limb bones during ambulation using the EksoTM system by Ekso Bionics. This information, in combination with selected clinical data, will be used to develop a model to predict the effects of exoskeleton-assisted gait training on bone health, muscle mass, and functional outcomes.

During the last year, the research team applied the advanced biomechanical models developed during the previous year to estimate the mechanical effects on the bone structures of exoskeleton-assisted gait in individuals with a complete SCI and collected data for a few of subjects. As we submit this annual report, we continue to actively schedule study volunteers for screening in order to reach the target sample size for the project.

Keywords

Biomechanical modeling, bone health, exoskeletons, gait, spinal cord injury.

Accomplishments

What are the major goals of the project?

The study specific aims, as indicated in the Statement of Work, are the following:

- (1) To quantify the motions of and forces transmitted through the lower extremities during exoskeleton-assisted gait;
- (2) To explore the development of a model to predict the effects of exoskeleton-assisted gait on bone health, muscle mass, and functional outcomes.

Specific Aim 1 is associated with three major tasks: 1) to obtain human subject approval and prepare for the study; 2) to contact and screen prospective study participants; and 3) to enroll study participants, train them with the exoskeleton and perform gait testing.

Specific Aim 2 is associated with two major tasks: 1) to explore ways of modeling the effects of exoskeleton-assisted gait; and 2) to perform data analysis.

What was accomplished under these goals?

Accomplishments for Aim 1:

Six subjects were found eligible for a final in-person screening at Spaulding Rehabilitation Hospital. Only three subjects met all the criteria, and agreed to participate either to the long term (one) or to the short term (two) analysis.

Data was collected by using the protocol previously developed. One subject completed all procedures; and the last subject enrolled in the study is currently undergoing training.

One subject (35 y.o. male, level of injury T4A) is currently finishing the 6-month training period and is scheduled to complete the study during the second week of December. Table 1 summarizes the data collected during the training sessions. All procedures carried out so far were well tolerated with no adverse events.

Table 1 Step length, swing time, walk and up time and number of steps for selected sessions of subject number 1.

Date	28-Apr	10-May	16-Jun	25-Jul	30-Aug	28-Sep	28-Oct	21-Nov
Step Length	12	14	17	16	16	16	16	16
Swing Time	1.3	1.3	1	1	1	1	1	1
Crutch/Walker Stand	Walker	Crutches	Crutches	Crutches	Crutches	Crutches	Crutches	Crutches
Walk Time	0:04:19	0:37:06	0:39:40	0:32:39	0:28:25	0:36:58	0:40:17	0:39:36
Up Time	0:17:11	1:02:50	1:09:53	0:36:25	0:30:54	0:39:34	0:41:52	0:40:50
Steps Taken with walker	59	-	-	-	-	-	-	-
Steps Taken with crutches	-	906	1192	1075	919	1237	1410	1450
Total Steps	59	906	1192	1075	919	1237	1410	1450
Final Assistive Device	Walker	Crutches	Crutches	Crutches	Crutches	Crutches		Crutches

The second subject (29 y.o male, level of injury T4A) was enrolled in the biomechanics portion of the study and completed all study procedures without adverse events.

The third subject (54 y.o. male, level of injury T9A) is starting the biomechanics portion of the study and is expected to complete the study procedures by the end of January 2017.

Accomplishments for Aim 2:

The kinematics of both the exoskeleton and the subject was collected together with the ground reaction forces. Torques applied by the exoskeleton were obtained via downloading data logged by the exoskeleton (Ekso Bionics). The data collected thus far is now ready for further analyses to be performed by the group at Worcester Polytechnic Institute (WPI).

In the first year, our research team developed experimental procedures and modeling techniques suitable to collect and analyze data recorded during exoskeleton-assisted gait in individuals with a complete SCI. In the following, we provide a summary of the techniques developed so far as part of the project.

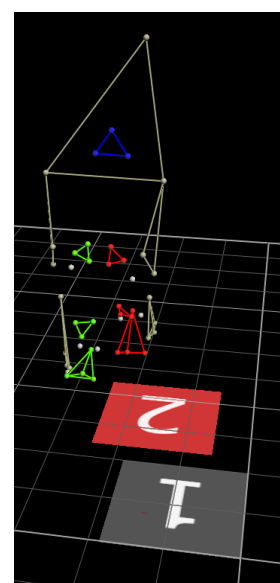


Figure 1. Motion Capture generated representation of subject and device

For all subjects, gait analysis was performed in the Motion Analysis Laboratory at Spaulding Rehabilitation Hospital after 6 weeks of training. The experimental set-up for the project relies upon two 6-channel force platforms (AMTI, Watertown, MA) embedded in a 12-m walkway that were used to record ground reaction forces and moments. A 10-camera motion capture system (Vicon, Oxford, UK) recording at 120Hz was used to track the kinematics and kinetics of gait (Figure 1). Passive reflective markers were attached using double-sided tape. Because it was not possible to place markers over anatomical landmarks as they were covered by the exoskeleton, the calibrated anatomical system technique (CAST) was used to model the lower extremity biomechanics [8]. This approach requires calibration of anatomical landmarks in order to calculate their position with respect to technical clusters of markers which can be freely placed on the user's body segments. Calibration was performed using a custom pointer which allowed the position of anatomical landmarks to be estimated even if their view was blocked by the exoskeleton.

To begin the experimental protocol, the mass and the height of the subject were measured together with the length of the limbs in order to properly setup the exoskeleton. The latter was achieved by means of parametric tables provided by Ekso Bionics. A physical therapist helped the subject to don the exoskeleton. Afterwards, marker clusters were placed on the subject as follows (see Figure 2):

- A cluster of three markers attached at pelvis height, directly on the rear of the exoskeleton, under the assumption that there was no relative motion between the pelvis and the portion of the exoskeleton attached to it;
- A cluster of three markers attached to each thigh;
- A cluster of three markers attached to each shank;
- A cluster of three markers attached to each foot.

Markers were then placed on the exoskeleton to aid in the estimation of its segment and joint kinematics. Data collection initiated with the calibration of anatomical landmarks which was carried out in a sequence of seated and standing positions. Anatomical landmarks to be calibrated included the tibial tuberosity, head of the fibula, medial and lateral epicondyles, medial and lateral malleoli, first/second/fifth metatarsal heads, heel, anterior superior iliac spines and posterior superior iliac spines. All calibrated landmarks were calibrated at the

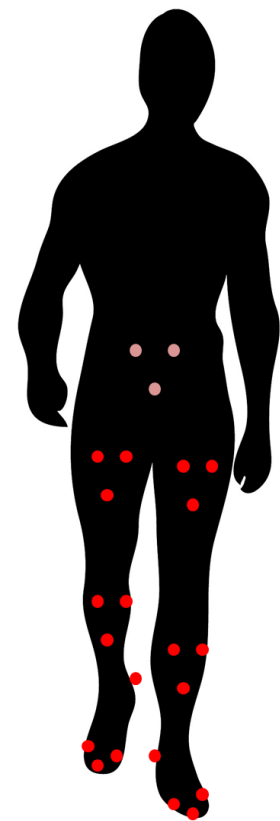


Figure 2. Schematic representation of how reflective markers are attached to different body segments to study the biomechanics of gait.

beginning of the data collection as static trials.

After the anatomical calibration, dynamic walking trials were performed until at least three walking trials with the subject stepping on a force platform with one foot were acquired. This was required for the computation of the inverse dynamics. Once all data was acquired, selected trials were labeled and gaps in the data were filled. The absolute positions of calibrated anatomical landmarks were computed in post processing from the clusters' positions and orientations obtained during these dynamic trials in order to calculate the kinematics and kinetics needed for said analysis. A data flow diagram is shown in Figure 3.

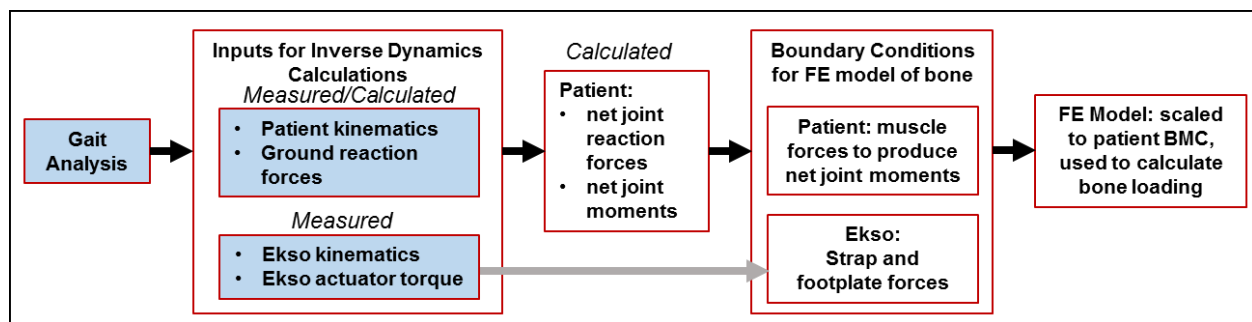


Figure 3. Data collection and flow. Shaded boxes indicate data that was collected and processed at Spaulding Rehabilitation Hospital. White boxes indicate calculations that are performed at WPI.

Processed motion capture data, force plate data, and information about knee and hip actuator torques obtained directly from the exoskeleton during walking trials were transferred to Karen Troy's team at Worcester Polytechnic Institute (WPI). Along with information about the patient and mechanical properties of the Ekso suit, masses and moments of inertia were used to calculate inverse dynamics of the patient+Ekso, henceforth referred to as the "lumped" model. Lumped inverse dynamics outputs consisted of net joint reaction forces and net joint moments at the ankle, hip, and knee.

The net forces and moments from the lumped model were separated into Ekso and patient forces and moments by subtracting the Ekso-actuator torques and the torques required to move the Ekso suit through the dynamic motion. **The results consisted of:**

- 1) net joint reaction forces, moments, and kinematics for the patient only, and**
- 2) actuator torques required to move the patient, which must be applied through the straps and foot-plates.**

For patients with complete spinal cord injury, we assumed that joint moments generated by the subject arose from one of three possible sources: 1) passive muscle resistance, which may be worse if contractures are present; 2) spasticity; 3) experimental error. For the purpose of defining user safety parameters, we used a “worst-case” bone loading scenario in which we assumed that

subject’s joint moments arose from spasticity contractions. In this approach, we calculated muscle length changes based on patient’s kinematics, and assigned activations to muscles crossing the joint from largest muscle to smallest, until the calculated net joint moment was achieved. **The result consisted of 1) muscle lines of action and activation forces during the gait cycle, and 2) joint *contact* forces at the ankle,**

knee, and hip. Note that joint contact forces were distinct from joint reaction forces, in that they represented the actual force transmitted from one joint surface to the next (e.g. tibia to femur), and were heavily influenced by muscle loading.

Joint contact forces, muscle forces, and Ekso strap and foot plate forces were looed upon as time-series data. These datasets represented the forces applied to the bones of the lower extremities. Bone stress and strain were calculated using scaled finite element (FE) models. “Generic” FE models of the femur and tibia were scaled such that their material properties reflected average values for an individual with chronic spinal cord injury, based on measured bone mineral content (BMC). When available, dual energy x-ray absorptiometry (DXA) measures of subject-specific BMC were used to provide a subject-specific scaling factor. Boundary conditions consisted of muscle forces, joint contact forces, and strap forces applied to the bone of interest. **The result was an estimate of the maximum energy equivalent strain, a scalar measurement shown to influence bone adaptation.** Factor of safety were also calculated; however, there is no validated method to accomplish this goal.

Once collected, the data was initially verified and processed with the Nexus software. Subsequently, a custom software platform [9] (Figure 4) was used to compute the positions of calibrated anatomical landmarks as well as the rotation and translation

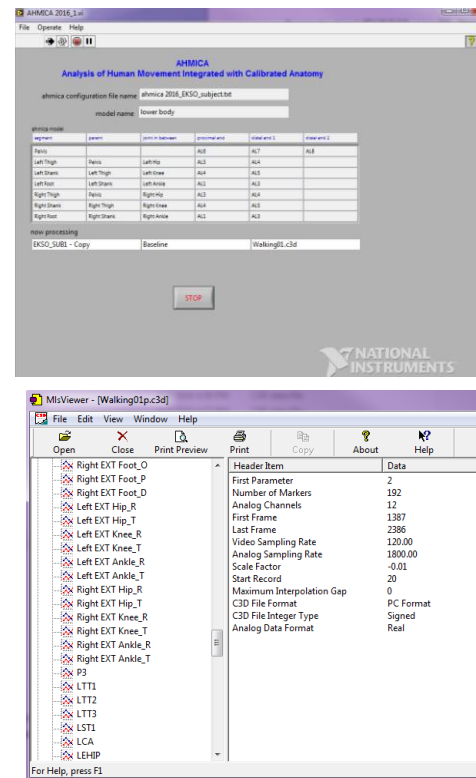


Figure 4. Software used for the analysis.

matrixes of the following lower body joints: right and left hip, right and left knee, right and left ankle. Furthermore, origins and proximal and distal position of the following segments was computed: right and left thigh, right and left shank, right and left foot. This was done for both the Ekso and the patients, considered as two different entities for analytic purposes.

All generated data was stored together with the position of the markers and the ground reaction forces in .c3d files. We worked in close collaboration with Ekso Bionics to download data logged by the exoskeleton: i.e. kinematics and actuator torques. Data collected so far is currently further analyzed by the research team at the Worcester Polytechnic Institute (WPI).

What opportunities for training and professional development has the project provided?

The project is not meant to create training and professional development opportunities.

How were the results disseminated to communities of interest?

We intend to start disseminating the results of the project as soon as we have completed the analysis currently undergoing at WPI.

What do you plan to do during the next reporting period to accomplish the goals?

Our primary goal is to continue collecting data from study volunteers and apply the biomechanical models developed so far to the datasets that will be collected from study volunteers. We anticipate continuing to derive biomechanical estimates of mechanical strain on bone structures as data is collected. We intend to correlate the estimated mechanical strain data with imaging data and physiological data that we are currently gathering longitudinally in the study population. Additional efforts will be made to recruit the remaining subjects in order to finalize the data collections and develop data driven algorithms to feed our prediction model.

Impact

What was the impact on the development of the principal discipline(s) of the project?

The work achieved so far has potential for significantly affecting the way exoskeleton-assisted gait is utilized in the clinic. Surprisingly, despite the enthusiasm in the clinical field for the use of robotic exoskeletons to enable gait in individuals with a complete SCI, clinical teams are not provided with appropriate tools to estimate or predict potential health benefits (e.g. bone health) associated with exoskeleton-assisted gait.

What was the impact on other disciplines?

The project that our team is carrying out is multidisciplinary in nature and hence the results of our studies are bounded to have an impact on multiple disciplines. Specifically, the biomechanical models that we have developed so far are expected to have a significant impact on the field of biomedical engineering. The primary impact of the experimental work that we are currently carrying out is expected to be clinical in nature. Overall, the combination of technical and experimental developments that are taking place as part of the project are expected to have a transformative impact on the clinical application of exoskeletons in individuals with a complete SCI.

What was the impact on technology transfer?

Although the project is not meant to generate results or products that would lead to a technology transfer, we anticipate that the methods that we have developed to estimate the effects on bone structures of exoskeleton-assisted gait will be of clinical interest. Hence, it is possible that the project might create technology transfer opportunities.

What was the impact on society beyond science and technology?

As we make progress with the project, we anticipate that the results of the studies to be carried out in individuals with a complete SCI will show the potential benefits of exoskeleton-assisted gait. Hence, the project might provide scientific evidence in support of the use of exoskeleton technology in individuals with SCI.

Changes and Problems

Changes in approach and reasons for change

The results achieved so far in the project have shown that the scientific approach that we originally proposed is valid. Hence, there has been no need to change the proposed scientific approach so far.

Actual or anticipated problems or delays and actions or plans to resolve them

After having experienced significant delays in obtaining IRB approval for the proposed experimental procedures last year, recruitment has been slower than anticipated. Hence, we would like to request a revision of the originally proposed timeline. We intend to discuss this matter with the program officer assigned to our project and kindly request authorization to revise the timeline that we originally proposed. Because of the complexity of the proposed experimental procedures, we would like to kindly request an extension of the project of approximately six months. As stated above, we will discuss this matter with the program officer assigned to our project.

Changes that had a significant impact on expenditures

None.

Other changes

None

Products

Publications, conference papers, and presentations

While we have not prepared any publication on this project as yet, we anticipate that we will soon start preparing a publication on the basis of the biomechanical and clinical data that we have and will continue to gather in the next phases of the study.

Technologies or techniques

We have developed software for the implementation of algorithms needed to study the biomechanics of exoskeleton-assisted gait in individuals with a complete SCI. This work is relevant to Specific Aim 1, Task 1. The specific implementation of the algorithms that we have adopted is an implementation that accounts for the small displacement between the exoskeleton and some of the body segments strapped to the exoskeleton. We have obtained IRB approval so that data can be collected from individuals with a complete SCI during exoskeleton-assisted gait. In parallel, Dr Troy's team at the Worcester Polytechnic Institute has worked on the experimental set-up for the computed tomography scans in addition to contributing to the development of algorithms to estimate mechanical strain on the bone structures. The work performed by Dr. Troy's team is relevant to Specific Aim 1, Task 1.

Participants & Other Collaborating Organizations

The following is the list of individuals who have worked on the project so far.

Name:	Paolo Bonato, PhD
Project Role	Principal Investigator
Institution	Spaulding Rehabilitation Hospital
Nearest Person Month Worked	1.60
Contribution to the Project	Dr Bonato has contributed to the development and amendment of the study protocol, the development of biomechanical procedures and algorithms for the study of exoskeleton-assisted gait, and the assessment of components of the camera-based motion capture system to evaluate their suitability for the study.

Name:	Leslie Morse, MD
Project Role	Co-Investigator
Institution	Spaulding Rehabilitation Hospital
Nearest Person Month Worked	1.24
Contribution to the Project	Dr. Morse has contributed to the development and amendment of the study protocol.

Name:	Karen Troy, PhD
Project Role	Co-Investigator (site PI)
Institution	Worcester Polytechnic Institute
Nearest Person Month Worked	1.60
Contribution to the Project	Dr. Troy has contributed to the development and amendment of the study protocol, the development of biomechanical procedures for the study of exoskeleton-assisted gait, the preparatory work to collect data using the scanning techniques at Worcester Polytechnic Institute.

In addition to the PI and Co-Investigators on the study, a research project coordinator (Mr. Ryan McIntosh), a post-doctoral student (Jean-Francois Daneault), three research therapists (Anne O'Brien, Cara Leone and Catherine Adans-Dester) and a research assistant (Eric Fabara) have assisted Dr. Bonato at Spaulding Rehabilitation Hospital.

Also, a research engineer (Nathan Smith) and a doctoral student (Ying Fang) have assisted Dr. Troy at the Worcester Polytechnic Institute.

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Quad Charts

The attached Quad Chart reflects the current status of the project and plans for the rest of the study.

Skeletal and Clinical Effects of Exoskeleton-Assisted Gait

Log Number A-18380

Award Number W81XWH-14-1-0611



PI: Paolo Bonato, PhD

Org: Spaulding Rehabilitation Hospital

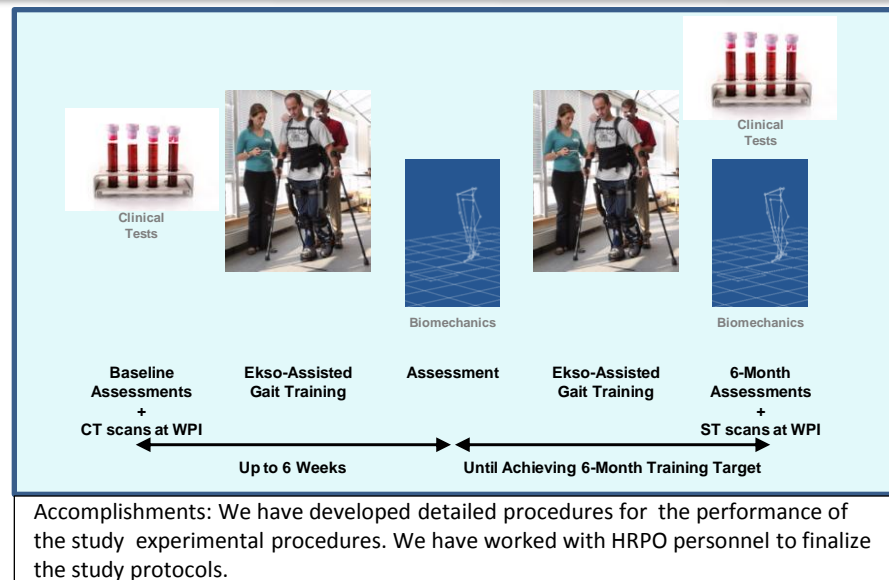
Award Amount: \$379,188

Study/Product Aim(s)

- To quantify the motions of and forces transmitted through the lower extremities during exoskeleton-assisted gait.
- To explore the development of a model to predict the effects of regular exoskeleton-assisted gait on bone health, muscle mass, and functional outcomes.

Approach

To achieve the above-stated specific aims, we plan to pursue the following tasks. Task 1.1: to obtain human subject approval and prepare for the study. Task 1.2: to contact and screen prospective study participants. Task 1.3 to enroll study participants and perform gait testing. These tasks are relevant to achieving Aim 1. Task 2.1: to explore modeling the effects of exoskeleton-assisted gait. Task 2.2: to perform data analysis. These tasks are relevant to achieving Aim 2.



Timeline and Cost

Activities	14	15	16	17
Approval study procedures and set-up				
Screen and enroll study participants				
Modeling effects of Ekso-assisted gait				
Data analysis				
Estimated Budget (~\$380K)	~\$60	~\$220	~\$80	~\$20

Goals/Milestones (Example)

CY14 Goal – Detailed description of protocols and procedures

- ☒ Evaluation of the procedures and data collection set-up

CY15 Goals – System validation

- ☒ Obtain protocol approval
- ☒ Screen and enroll study volunteers
- ☒ Complete studies in a subset of subjects

CY16 Goal – Production readiness

- ☐ Complete studies in all subjects
- ☐ Perform data analysis

Comments/Challenges/Issues/Concerns

- If timelines change, comment here.
- If off by more than one quarter in spending, comment here.

Budget Expenditure to Date

Projected Expenditure: ~\$360K

Actual Expenditure: ~\$360K

Updated: August 11, 2016